FUJIFILM FUJINON

K063316
pg 1 of 3

510 (k) Summary

MAR 16 2007

Date Prepared [21 CFR 807.92(a)(1)]

10/26/06

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Fujinon Inc.

Contact:
Joseph Azary
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Sponsor / U.S. Distributor:
Fujinon Inc.
10 High Point Drive
Wayne, NJ 07470
FDA Establishment Registration# 2431293.

Manufacturer:
Fujinon Corporation
1-324 Uetake-Cho
Kita-Ku, Saitama-Shi
Saitama 331-9624, Japan
FDA Establishment Registration# 9610875

K063316

Pg 2 of 3

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade Name: Fujinon EG-530N

Device Common, Usual, or Classification Names: Gastroscope

Classification: Class II, 21 CFR 876.1500, FDS

Predicate Device [21 CFR 807.92(a)(3)]

- Fujinon EG-450WR5 (K042043)

The subject device have the **same** indications for use, material composition, viewing direction, image size, bending, reprocessing/sterilization method, and working dimensions as the predicate. The subject device uses the same processor and peripherals as the predicate device.

The main differences between the EG-450WR5 and the EG-530N are as follows:

- Minor differences in Field of View
- Smaller diameter of distal end and flexible portion
- Smaller diameter of Forcep channel
- The addition of the trans nasal indication

Trans Nasal insertion for gastroscopes has received FDA marketing clearance in the following 510(k) Pre-market Notifications:

- K001766 Olympus XGIF-N200H

The EG-530N has the same indications for use, similar diameter and working channel as the Olympus device.

Description of the Device [21 CFR 807.92(a)(4)]

The device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The device can be inserted orally or trans nasally.

The EG-530N consists of the following portions / parts:

- Control portion – to provide grip for holding the endoscope and for the operation of the endoscope.
- LG Flexible Portion – Contains the light guide, air/water supply tube, suction tube, and cables.
- Bending Portion
- Distal End – Contains objective lens, air/water nozzles, forceps channel.

The EG-530N is used with a Processor (4400) and other peripheral items such as VCR, Television Monitor, and Printers. The Product Specifications document (89A71999A01) has been included in Annex 5.

K 063316

Pg 3 of 3

Specifications Chart:

		EG-530N
Viewing Direction		Forward
Observation Range		3-100mm
Field of view		120 degrees
Image size		Super Image
Distal end diameter		5.9 mm
Flexible portion diameter		5.9 mm
Up	Bending capability	210 degrees
Down		90 degrees
Left		100 degrees
Right		100 degrees
Forceps channel diameter		2.0mm
Working length		1100mm
Total length		1400mm
Processor		400 Series

Intended Use [21 CFR 807.92(a)(5)]

The device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The device can be inserted orally or trans nasally.

Technological Characteristics [21 CFR 807.92(a)(6)]

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device have the **same** indications for use, material composition, viewing direction, image size, bending, reprocessing/sterilization method as the predicate. The subject device uses the same processor and peripherals as the predicate device.

The main differences relate to the trans nasal insertion and the smaller diameter of the device compared to the Fujinon G5 Gastroscopes.

Transnasal insertion of gastroscopes (or any type of endoscopes) is a method in use for several years. It is a viable option for patient's that gag easily or feel uncomfortable with oral insertion of scopes.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed electrical safety, thermal, and EMC testing requirements. The materials in the endoscope are identical to the materials used in the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 16 2007

FUJINON, Inc.
c/o Mr. Joseph M. Azary
Azary Technologies LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K063316
Trade/Device Name: Fujinon EG-530N Trans Nasal Insertion
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated: February 22, 2007
Received: February 26, 2007

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 063316

Device Name: Fujinon EG-530N Trans Nasal Insertion

Indications For Use:

The device is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenal bulb. The device can be inserted orally or trans nasally.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063316